

C2
Sub F2

18. (amended) A method of producing a plant of the chicory genus or reproducing material of a plant of the chicory genus exhibiting cytoplasmic male sterility, comprising integrating a nucleotide sequence conferring male sterility borne by a sunflower orf 522 sequence or by a male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein said sunflower orf 522 sequence or said male-sterility-conferring sequence comprises polynucleotide sequences having the sequence shown in SEQ ID NOS:1 and 2.

REMARKS

Claims 12-19 are pending. Claims 13, 14, and 19 are withdrawn from consideration as constructively elected. The amendment to claims 12 and 18 is supported throughout the specification. Claims 12 and 15-18 are thus presented for reconsideration in view of the remarks below.

1. *Rejection under 35 U.S.C. § 112, first paragraph: requirement for adequate written description.*

Claims 12 and 15-18 are rejected under the first paragraph of Section 112, because the skilled artisan allegedly would not reasonably think that applicant had possession of the claimed invention at the time of filing. This conclusion is apparently founded on two suppositions.

First, the examiner alleges that the specification does not describe the protein encoded by the orf 522 nucleic acid or the mechanism by which the encoded protein alters plant fertility. The sequence of orf 522 is described at page 2, lines 3-7, with reference to a research publication by Köhler *et al.* in *Molecular & General Genetics*, volume 227, pages 369-376 (1991). The complete nucleotide sequence of orf 522 and the deduced protein sequence are shown in Figure 2 of Köhler. Because this description provides an adequate written description of this aspect of the claimed invention, this part of the rejection should be withdrawn. A disclosure of the mechanism by which orf 522 alters fertility is unnecessary. It is axiomatic that "an applicant need not understand the theory or scientific

principle underlying his invention” to comply with Section 112. *In re Issacs*, 146 U.S.P.Q. 193, 197 (CCPA 1965).

Second, the examiner alleges that the specification does not describe the characteristics of a donor genome, in terms of an identifiable physical or chemical property that would confer a male-sterile phenotype. The claimed plant genome comprises the sunflower orf 522 sequence or a sequence with at least 50% homology to that sequence. See the paragraph bridging pages 2 and 3. Contrary to the Examiner’s allegation that the specification does not describe donor genome characteristics indicative of the male-sterile phenotype, Example 2 details PCR analyses that demonstrate the presence of orf 522 in male sterile plants and the absence of this sequence in all normal chicory plants. The examiner’s statement that there are no physical or chemical properties that correlate to the expression of cytoplasmic male sterility is disproved by this description.

2. *Rejection under 35 U.S.C. § 112, first paragraph: requirement for an enabling specification.*

The claims are rejected under Section 112, first paragraph, because those skilled in the art allegedly would not be enabled to practice methods in the specification.

The Examiner first alleges that the claims encompass a method of making cytoplasmic male-sterile (CMS) chicory plants that the specification does not describe, but that Araya describes as “not reliable or reproducible.” Column 2, lines 1-2. Taken in context, Araya refers to the use of alloplasmic systems to create CMS plants, in which backcrosses are used to substitute the nuclear genome of one species with another. This nuclear substitution leads to CMS through an incompatibility between the nucleus and cytoplasm. See Araya at column 1.

The specification describes the successful production of CMS plants by protoplast fusion according to a modification of the method of Kao (second full paragraph of page 6), which resulted in the production of a CMS plant with a chicory phenotype (first full paragraph of page 7). Thus, applicants already have accomplished through routine methodology what the Examiner alleges the artisan cannot do without undue

experimentation. In contrast to the Examiner's allegation, the specification provides sufficient guidance to predictably make CMS plants having a chicory phenotype. Because the Examiner has not shouldered her burden of providing a clear line of reasoning or evidence why the claims are non-enabled, especially in view of this evidence to the contrary, the rejection is improper and should be withdrawn. *See In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

The Examiner further alleges that the specification does not describe the biochemical mechanism by which male sterility is conferred. A disclosure of the mechanism by which orf 522 confers sterility is unnecessary to comply with the enablement requirement of Section 112, just as it not required to comport with the written description requirement of this Section. Again, "an applicant need not understand the theory or scientific principle underlying his invention" to comply with Section 112. *In re Issacs*, 146 U.S.P.Q. at 197. In this same part of the rejection, the Examiner further alleges that the specification does not describe the "interaction of [the orf 522] gene product in the genome of any other plant species." The claims recite that the subject plants belong to the genus of chicory plants, so it is irrelevant whether orf 522 could lead to CMS in plant species other than those of the chicory genus. With respect to plant species within the chicory genus, the specification exemplifies producing a CMS plant of *Cichorium intybus* L. cv. *Pévèle*. The Examiner has presented no evidence or line of reasoning, as she must, to substantiate the allegation that success in one chicory species would not be predictive of success in any other chicory species. *See In re Marzocchi*, 169 U.S.P.Q. 367 (CCPA 1971).

The Examiner further alleges that claim 18 is non-enabled because no method of reproducing the male-sterile chicory plant is described, such as by the use of a restorer line. The Examiner cites Yan for the propositions that such restorer lines are difficult to find and that high ploidy levels complicate this method through adding instability to CMS breeding systems. The Examiner has not made it clear why these teachings are relevant to the claimed invention. The specification addresses the reproduction of CMS chicory plants at page 1, where applicants propose CMS as a *solution* to problems with producing hybrid chicory species. Chicory possesses both female and male reproductive systems, and

because CMS does not affect female sterility, the CMS plants may be crossed with male fertile chicory plants. Because applicants have provided a solution to whatever problems may exist for reproducing a chicory plant exhibiting CMS, undue experimentation is not required to practice the claimed method. Accordingly, the rejection should be withdrawn.

3. Rejection under 35 U.S.C. § 102(b).

Claims 12 and 15-17 are rejected under 35 U.S.C. § 102(b) as anticipated by Rambaud (1994), which allegedly teaches the production of male sterile plants through protoplast fusion of chicory and CMS sunflower. Applicants respectfully traverse the rejection.

For a reference to anticipate an invention within the meaning of Section 102, it must teach each and every element of the claims. *In re Bond*, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Applicants have characterized the teachings of Rambaud (1994), and they incorporate those remarks in their entirety here by reference. Rambaud's technique for creating CMS plants necessitates rearrangements of the mitochondrial genome. See, for example, Rambaud (1993). Although Rambaud (1994) allegedly describes the detection of orf 522 in the CMS genome, he does not determine whether the orf 522 sequence comprises a polynucleotide sequences having the sequence shown in SEQ ID NOS:1 and 2. The mere **possibility** that one of these plants contains such a polynucleotide sequence within it is insufficient to predicate a rejection under Section 102. It is well established that a property allegedly inherent in the prior art must flow **necessarily** from the art teachings. As the Examiner's own reviewing court has held, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). See also MPEP § 2112, stating "[t]he fact that a certain result or characteristic **may** occur in the prior art is not sufficient to establish the inherency of that result or characteristic" (emphasis in original). For a claim to be inherent disclosed in the prior art, it is insufficient that a person following the disclosure sometimes obtains the result set forth in the claim. It must happen invariably. *Glaxo, Inc. v. Novopharm Ltd.*, 830 F. Supp. 871, 874 (E.D. N.C. 1993). Since the Examiner has not provided the

requisite evidence or reasoning to establish that the CMS plants allegedly obtained by Rambaud (1994) contain the claimed sequences, Rambaud (1994) does not anticipate the claimed invention, and the rejection may now be withdrawn.

4. *Rejection under 35 U.S.C. § 103(a).*

In Section 5 of the office action, claims 12 and 15-18 stand rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Rambaud (1994), Rambaud (1993) and Laver et al. (1991). Applicants traverse the rejection.

None of the cited references disclose or suggest a polynucleotide comprising a sequence as shown in SEQ ID NOS:1 and 2. The principal reference, Rambaud (1994), only invites further experimentation to try to establish the identity of the DNA sequence(s) that conferred CMS, *supra*. Such an invitation provides no more than “general guidance as to the particular form of the invention or how to achieve it.” *In re O’Farrell*, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988); *see generally* MPEP § 2145. Neither of the other cited references disclose added information that would have provided more guidance than Rambaud (1994). Thus, neither Rambaud (1994) nor the proposed combination of references evidence a reasonable expectation of success at uncovering a polynucleotide comprising both SEQ ID NOS:1 and 2, as claimed. At best, these references would have motivated the artisan to try to make the claimed invention. However, it is well established that “obvious to try” is not a proper standard for applying a rejection under Section 103. *Id.* Thus, the rejection is improper and should be withdrawn.

CONCLUSION

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date Nov. 6, 2001

By Brian K. Lathrop

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5300
Facsimile: (202) 672-5399

Brian K. Lathrop
Agent for Applicants
Registration No. 43,740

Marked up version of the amended claims

12. (amended) A recombinant plant genome comprising at least one chicory gene and a nucleotide sequence conferring male sterility borne by a sunflower orf 522 sequence or by a male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein said sunflower orf 522 sequence or said male-sterility-conferring sequence comprises polynucleotide sequences having the sequence shown in SEQ ID NOS:1 and 2.

18. (amended) A method of producing a plant of the chicory genus or reproducing material of a plant of the chicory genus exhibiting cytoplasmic male sterility, comprising integrating a nucleotide sequence conferring male sterility borne by a sunflower orf 522 sequence or by a male-sterility-conferring sequence with at least 50% homology with the sunflower orf 522 sequence, wherein said sunflower orf 522 sequence or said male-sterility-conferring sequence comprises polynucleotide sequences having the sequence shown in SEQ ID NOS:1 and 2.